endocare.

# Attachment 5

## 510(k) Summary

**Prepared November 7, 2002**

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| **TRADE NAME** | **Cryocare Surgical System** | | |
| **CLASSIFICATION** | **Class II (21 CFR 878.4350)** | | |
| **SUBMITTED BY** | Endocare, Inc.<br>201 Technology<br>Irvine, CA 92618 | **CONTACT** | Eben Gordon<br>Regulatory Affairs<br>949.450.5424<br>949.450.5300 |
| **PREDICATE DEVICE** | K011074 Cryocare Surgical System<br>Decision date: January 25, 2002 | | |
| **DEVICE DESCRIPTION** | The Cryocare Surgical System consists of a compact, easy-to-operate console and associated accessories that include CryoProbes to deliver cold temperatures to the targeted tissue and TempProbes to monitor temperatures in the surrounding tissue.<br>The control console operates off standard 120/230 VAC (60/50 Hz) wall power and utilizes inert Argon gas. The console can control up to eight, single-use, disposable CryoProbes.<br>The CryoProbes operate on the Joule-Thompson Principle and the refrigerative capacity is limited to the distal tip of the probes. Each CryoProbe incorporates a thermocouple to monitor probe temperature.<br>Helium gas is used after the freezing process. As the gas passes through the J-T port, there is a significant pressure drop which conversely results in an increase in the gas temperature.<br>The console can also monitor up to eight independent TempProbes. The TempProbes are standard T-type needle thermocouples.<br>An IBM-compatible microprocessor serves as the host computer. System control is accomplished through a remote control keypad.<br>The system can be operated manually or using the AutoFreeze option, which allows users to pre-program specific treatment parameters. | | |

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| **INDICATIONS FOR USE** | The Cryocare Surgical System has the **same intended use** as previously cleared for the Cryocare Surgical System - K011074.<br><br>The Cryocare Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. |
| **TESTING** | In-vitro testing of the Cryocare Surgical System included time and temperature performance under simulated use conditions. Software validation was performed in accordance with IEC 60601-1-4 and the General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002).<br><br>All testing of the product yielded acceptable results. |
| **SUMMARY OF SUBSTANTIAL EQUIVALENCE** | The modified Cryocare Surgical System is substantially equivalent to the predicate device in intended use and principles of operation. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2002

Endocare, Inc.
Eben Gordon
Sr. Director of Regulatory Affairs
201 Technology Drive
Irvine, California 92618

Re: K023757
Trade/Device Name: Cryocare Surgical System, Model Cryo 20
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: November 7, 2002
Received: November 8, 2002

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Attachment 2

## Indications for Use Statement

510(k) Number: K023757

Device Name: **Cryocare Surgical System**

Indications for Use:

The Cryocare Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition the system is intended: for use in the following indications:

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023757

**Prescription Use** X **(Per 21 CFR 801.109)**

## Indications for Use Statement (Continued)

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Neurology

- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

for Mark N Melkerson

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**Prescription Use __X__ (Per 21 CFR 801.109)**

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